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DATE MAILED: 10/23/2003

APPLICATION NO.	FI	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,972 09/17/2001		George Jackowski	21,32.074	7710	
21917	7590	10/23/2003		*I EXAMINER	
MCHALE (	& SLAV	N, P.A.	NGUYEN, BAO THUY L		
2855 PGA B	LVD	-			
PALM BEACH GARDENS, FL 33410				ART UNIT	PAPER NUMBER
		.,		1641	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
•	09/954,972	JACKOWSKI ET AL.					
Office Action Summary	Examiner	Art Unit					
	Bao-Thuy L. Nguyen	1641					
Th MAILING DATE of this communication app ars on the cover sh t with th correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period was a failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  Status	16(a). In no event, however, may a reply be tin within the statutory minimum of thirty (30) day fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).					
1) Responsive to communication(s) filed on 17 S	September 2001 .						
2a) ☐ This action is <b>FINAL</b> . 2b) ☐ Thi	is action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the ments is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4)⊠ Claim(s) <u>1-20</u> is/are pending in the application							
4a) Of the above claim(s) is/are withdrawn from consideration.							
^ 5) ☐ Claim(s) is/are allowed.							
6) Claim(s) is/are rejected.							
<ul><li>7) ☐ Claim(s) is/are objected to.</li></ul>							
8) Claim(s) <u>1-20</u> are subject to restriction and/or e	election requirement.						
Application Papers  9)  The specification is objected to by the Examine	r						
,		miner					
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13)	prionty under 35 U.S.C. § 119(a	a)-(d) or (f).					
a) ☐ All b) ☐ Some * c) ☐ None of:		•					
1. Certified copies of the priority documents	s have been received.						
2. Certified copies of the priority documents	s have been received in Applicat	ion No					
<ul> <li>Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received.  15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)					
J.S. Patent and Trademark Office	Ai C	Part of Paner No. 8					

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## Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - Claims 1-2, drawn to a diagnostic marker, classified in class 530, subclass 380, for example.
  - II. Claims 3-6, drawn to a test kit, classified in class 422, subclass 58, for example.
  - III. Claims 7-10, drawn to a method for Schwann cell analysis, classified in class 435, subclass 7.1, for example.
  - IV. Claim 11, drawn to a test kit for having antibody to GFAP, classified in class 436, subclass 536, for example.
  - V. Claim 12, drawn to an anti-GFAP IgG, classified in class 530, subclass 387.1, for example.
  - VI. Claim 13, drawn to prediabetic screening assay, classified in class 435, subclass 7.92, for example.
  - VII. Claims 14-15 and 20, drawn to a method for treating a disease process, classified in class 424, subclass 184.1, for example.
  - VIII. Claims 16-19, drawn to screening assay, classified in class 530, subclass 412, for example.
- **2.** The inventions are distinct, each from the other because of the following reasons:

Inventions I, II, IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together. The kits of Groups II and IV do not require the diagnostic marker of Group I. The diagnostic marker of Group I is different

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from the antibody of Group V and has different modes of operation and different function. The marker of Group I is also not disclosed as capable of use together with the screening assay and method of treatment of groups VI – VIII.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used to recover and purified Schwann cell proteins.

Inventions II and III-VIII are unrelated because they have not been disclosed as capable of use together.

Inventions III and IV-VIII are unrelated because they have not been disclosed as capable of use together, have different modes of operation and different effects.

Invention IV and V-VIII are unrelated because they have not been disclosed as capable of use together, have different modes of operation and different effects.

Inventions V and VI-VIII are unrelated because they have not been disclosed as capable of use together, have different modes of operation and different effects.

Inventions VI and VII-VIII are unrelated because they have not been disclosed as capable of use together, have different modes of operation and different effects.

Inventions VII and VIII are unrelated because they have not been disclosed as capable of use together, have different modes of operation and different effects.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search

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required for Group I is not required for Group II-VIII, restriction for examination purposes as indicated is proper.

- **4.** Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
- 5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- **6.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Tuesday Thursday from 9:00 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Bao-Thuy L. Nguyen Primary Examiner

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